

Attorney Docket No. UAB-15102/22

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant: Jay M. Meythaler et al.

Serial No.: 10/049,327

Group Art Unit: 1617

Filing Date: May 15, 2002

Examiner: Kathrien Ann Cruz

For: METHOD OF TREATING TRAUMATIC BRAIN AND SPINAL CORD
INJURIES AND OTHER NEUROGENIC CONDITIONS USING
NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND NATURALLY
OCCURRING CONOTOXINS

APPELLANT'S REPLY BRIEF UNDER 37 CFR §41.41

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 37 C.F.R. 41.41, this reply brief is filed within two months of the Examiner's Answer.

RESPONSE TO EXAMINER'S ARGUMENTS

Throughout the remaining rejections under 35 U.S.C. §103(a), one inescapable truth exists: none of the cited prior art teaches treatment with the only claimed compound – choline magnesium trisalicylate (CMT), or prodrug thereof. Examiner has only hindsight in view of Appellants' disclosure for any suggestion to use CMT as a therapeutic.

Breitner, the only reference that mentions CMT, is directed to prevention or delaying the onset of Alzheimer's disease by administration of an NSAID to at risk people. One of ordinary skill in the art has no reasonable expectation of success for treating a neurotrauma by administration of CMT from any teaching of Breitner simply because Breitner does not examine treatment of any neurotrauma. Breitner associates delayed disease onset with past use. No data, chart, statement, or suggestion in Breitner indicates that the unique properties of CMT such as Ca^{2+} effects and amelioration of remote secondary damage resulting from neurotrauma are necessary or have any role in prevention.

Examiner concludes that all NSAIDS are equivalents for the treatment of neuro-related disorder so that administration of CMT for neurotrauma must be obvious. This position is simply not borne out by the pharmacological literature as understood by one of skill in the art or indeed a layperson who recognizes that aspirin, ibuprofen, and acetaminophen each have unique attributes and contraindications.

While Grilli does state treatment with ASA or NaSal, Grilli also teaches, in contrast, that indomethacin (another NSAID) was "unable to prevent glutamate-evoked cell death." (page 9, lines 10-13.) Together these teachings reveal that all NSAIDs are not equal when used for treatment. Thus, the unsupported statement in Grilli that ASA or NaSal are effective treatments of Alzheimer's disease does not provide a reasonable expectation of success using other NSAIDs or specifically CMT for treatment of neurotrauma or neuronal injury.

A lack of any reasonable expectation of success is further supported by Grilli "surprisingly" finding that only NSAIDs of their formula I are suitable for treatment of neuronal damage. (See paragraph bridging pages 4-5.) CMT is not encompassed by their formula I with at least two different substitutions on the central ring. It certainly was surprising to Grilli that any NSAID could function as a therapeutic given that Breitner (filed four years earlier) did not show any such success with any NSAID. Since Grilli teaches that NSAIDs are not equivalent and were surprised by the activity of their formula I compounds, one of ordinary skill in the art has no reasonable expectation of success that compounds other than Grilli formula I would have any success in treatment of neurotrauma.

Examiner concludes:

It would have been obvious to administer CMT for delaying the onset of Alzheimer's disease or related neurodegenerative disease as taught by Breitner and to further employ deacetylated aspirin for the treatment of Alzheimer's disease associated with neuronal injuries because it is known in the art that non-steroidal anti-inflammatory drugs can be used in the treatment of glutamate receptor-mediated neuronal damages. (Examiner's Answer, sentence bridging pages 8-9.)

Appellants take no stance on whether it would be obvious to administer CMT for prevention of Alzheimer's or to administer deacetylated aspirin for treatment of Alzheimer's. The claims are not directed to such prevention or to administration of aspirin. Instead, the claims are narrowly tailored to treatment of neurotrauma with CMT or its prodrugs, and this claimed method is non-obvious over the cited prior art.

Overall, the cited prior art is wholly lacking a teaching of any treatment of neurotrauma with CMT or any suggestion that such administration will work. The clear unpredictability taught by Grilli, and recognized in the art, concerning whether a NSAID will work in treatment neurotrauma reveals that one of ordinary skill in the art has no reasonable expectation of success by administering CMT for the treatment of neurotrauma as required by the pending claims. For at least this reason, Appellants respectfully request that all outstanding rejections be REVERSED.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180, under Order No. UAB-15102/22.

Date: September 3, 2010

Respectfully submitted,

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